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09/870,009	05/30/2001	Hisashi Kashima	JP920000069US1	8419

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EXAMINER

SMITH, CAROLYN L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/870,009

Applicant(s)

KASHIMA ET AL.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003 and 12 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,8-12 and 15-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,8-12 and 15-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 12022003.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10222003. 6) ☐ Other:

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submissions, filed 10/15/03 and 11/12/03, have been entered.

The amendment of claims 5, 8, 11, 12, 15, 16, 18, 23, 24, and 27, filed 10/15/03, are acknowledged.

During an in-person interview on 12/2/03, Attorney Miller and Examiners Smith and Marschel discussed the NEW MATTER and prior art rejections of the previous amendment and discussed proposed amendments.

The information disclosure statement (IDS), filed 10/22/03, fails to comply with the provisions of 37 CFR 1.97, 1.98, and MPEP § 609, because references (Hara and Nakayama, on page 1 of the IDS) are in a foreign language. The abstract of the Katsumata et al. reference (page 2) has been considered as it is in English. However, the remainder of the reference has not been considered, because it is in a foreign language. A translation of these references is needed if Applicants want these references to be considered. These references have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the

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date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609, ¶ C(1).

Claims herein under examination are 5, 8-12, and 15-27.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5, 8-12, 15, and 17-27 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims 5, 8-12, 15, and 17-27 do not sufficiently distinguish over nucleic acids and cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. It is acknowledged that insertion of special and non-natural sequences is described in the specification, but not particularly in these claims. Thus, one interpretation of the claims is that they are inclusive of DNAs wherein a watermark sequence is merely recognized in a naturally occurring DNA. In the absence of the hands of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

Applicants state that the Court used a test for patentable subject matter regarding the result of human intervention. Applicants further state that the Court held “nonnaturally

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occurring manufacture or composition of matter” to be patentable subject matter. While this is true, the instant claims are broadly and reasonably interpreted to encompass naturally occurring products that are considered nonstatutory subject matter, as described above. Applicants state that the claims include recitations that clarifies some human intervention. This is found unpersuasive as the claims in their broadest and reasonable interpretation do not necessarily include human intervention. For example, claim 5 states “DNA to which information is added” which can occur via evolution or mutation that is independent of the hands of man. Applicants’ arguments regarding a nucleotide sequence which is added are found unpersuasive as this “added” limitation is considered NEW MATTER, as described below.

Claims Rejected Under 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION

Claims 5, 8-12, and 15-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

The specification does not appear to provide support for phrases “nucleotide sequence which is added to” (claim 5, line 4 and claim 12, line 4), “added to” (claim 15, line 4), “added” (claims 22 and 26), or “being added” (claims 1, 12, and 15). Written basis is provided for a

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sequence being embedded (i.e. original claim 8), but not for the broadly mentioned act of “being added” which has a broader scope than the support provided in the specification. Figure 3 depicts inserting a watermark sequence, but this does not provide adequate support for the broadly mentioned “nucleotide sequence which is added to” which differs in scope. Also, the specification does not appear to provide support for the phrase “added to and” (in instant claims 8 and 11), “comprises a plurality of sequences having a plurality of types of patterns embedded at predetermined locations in said second portion” (in instant claim 18, and “corresponds to a source of” (in instant claim 27). Because the introduction of “nucleotide sequence which is added to”, “added to”, “added” “being added”, “added to and”, “comprises a plurality of sequences having a plurality of types of patterns embedded at predetermined locations in said second portion”, and “corresponds to a source of” lacks written basis for amended claims 5, 8, 11, 12, 15, 18, 22, 26, and 27, filed on 10/15/03, these phrases are considered NEW MATTER. Claims 9-10, 16-17, and 19-21, and 23-25, are also rejected due to their direct or indirect dependency from claims 8 and 15.

The amendment (new drawings) filed 10/16/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: replacing the nucleotide base letters with “X”s, such as in Figures 8 and 9. Written basis is provided for the phrase “insert a watermark sequence”, such as in Figure 3, but not for an actual replacement of nucleotide base letters as is now found in Figures 8 and 9. Because of introduction of “X”s in Figures 8 and 9 lacks written basis, filed 10/16/03, these “X”s are considered NEW MATTER.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 8-12, and 15-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 5, 12, and 15 recite the phrases “a portion, other than said gene portion, including no genetic information”, “said portion including no genetic information”, “a second portion which is devoid of genetic information” which are vague and indefinite. It is unclear how a portion of DNA can be considered not to have genetic information when it is well known in the art that DNA is made up of nucleotides which are considered to be genetic information. Clarification of this issue, via clearer claim wording, is requested. Claims 16-27 are also rejected due to their direct or indirect dependency from claim 15.

Claims 5, 8, 11, 12, and 15 recite the phrase “so as not to affect transmission of said genetic information” which is vague and indefinite. It is unclear if the transmission is directed to passing genetic information to other cells or organisms, passing information via transcription and translation, or passing information from one physical location to another. Clarification of this

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issue via clearer claim wording is requested. Claims 9-10 and 16-27 are also rejected due to their direct or indirect dependency from claims 8 and 15.

Claim 17 recites the phrase “provided by one of selective breeding, cultivation, and gene manipulation” which is vague and indefinite. If the provision is accomplished by “one” then it is unclear why “and” is used in the phrase. Clarification of whether all or just one of the provisions is required is needed.

Claim 24 recites the phrase “comprises one of a restrictive enzyme identification sequence and a promoter” which is vague and indefinite. It is unclear if both the restrictive enzyme identification sequence and a promoter are required or if one of each is required. Clarification of this issue via clearer claim wording is requested.

Applicants submit that the use of the phrase “one of x, y, and z” is common and customary claim language and is perfectly acceptable U.S. practice. This is found unpersuasive as each patent and patent application is examined under its own fact pattern. In addition, the two latter rejections above have various interpretations (as pointed out in the rejections) and are therefore rejected due to the unclarity of their intended meanings.

Prior art rejections

A new prior art reference is being applied to the instant invention.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 8-12, and 15-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Dollinger (P/N 5,451,505).

Dollinger discloses nucleic acids which are used as taggants that allows for subsequent identification of a substance, product identity (col. 1, lines 11-16 and 25-27). Dollinger discloses a taggant as a nucleic acid that comprises a specific nucleotide sequence or composition (col. 2, lines 59-62). The term “genetic information” used in the claims lacks clarity, but the nucleotide sequence can be considered to be genetic information in the sense that it contains nucleotides. Dollinger discloses any substance may be used for tagging by treating the substance with a nucleic acid taggant (col. 1, lines 50-54). Dollinger discloses nucleic acids that are covalently bound to the tagged material (including the taggant) (col. 2, lines 15-18) which is reasonably interpreted to be a gene portion and other portion (taggant), as stated in instant claim 5. Dollinger discloses tagging any substance with a nucleic acid taggant so that the nucleic acid attaches to the material (col. 1, lines 50-54). Dollinger discloses the nucleic acid taggant comprises a specific nucleotide sequence or a composition of specific nucleotides to facilitate tracing or determining the origin or source of a material (col. 1, lines 54-60 and col. 3, lines 7-8). Dollinger discloses the nucleic acids can be either naturally occurring or synthetically derived (col. 2, lines 6-7), as stated in instant claim 16, as well as not being naturally generated through gene mutation (as stated in instant claim 23). Dollinger discloses the taggants are typically non-biologically functioning and are not part of a functional nucleic acid sequence operating in a

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living cell (col. 2, lines 62-65) which is reasonably interpreted to mean the taggant sequence does not affect transmission of biologically functional genetic information (as stated in instant claims 5, 8, 12, and 15). Dollinger discloses using combinations of sequences and varying levels of specific sequences to identify the product, product's origin, the lot or batch, or an identifier for a unit of commerce (col. 3, lines 22-28) as well as using a sequence with multiple regions of specificity (col. 5, lines 9-11) which is reasonably interpreted to encompass multiple patterns at predetermined locations, as stated in instant claims 9, 10, 18, 19, and 20. The instant specification, page 1, second paragraph, defines "value-added genes" as having properties or values rated and levels assigned and creating added value to the gene. Dollinger discloses tracking animals and plants (gene bearing organisms) (col. 1, lines 17-19) which is reasonably interpreted to be determining product identity for cultivation or breeding purposes including value-added genes, as stated in instant claim 17. Dollinger discloses amplifying the sequence prior to detection via polymerase chain technology (col. 2, lines 3-5) which is reasonably interpreted to mean being copy tolerant, as stated in claim 21. Dollinger discloses the nucleic acids may be bound to solid support (devoid of genetic information and predetermined location) that is then mixed with the material being tagged (col. 2, lines 23-26), as stated in instant claim 15. Dollinger discloses tagging methods involve detection and PCR technology where the nucleic acid must form duplexes with primers (complementary sequence) (col. 3, lines 41-47) and using hybridization techniques (col. 6, lines 3-20), as stated in claim 25. As it is unclear if instant claim 24 requires either a restriction enzyme identification or a promoter or both, Dollinger discloses promoters can be incorporated in the primers (col. 5, lines 47-51), as stated in

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claim 24. Dollinger discloses use of a taggant of a sequence complementary to the DQ α allele (gene) (col. 6, lines 55-56).

Thus, Dollinger anticipates the instant invention.

Conclusion

No claim is allowed.

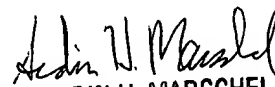
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 23, 2003


ARDIN H. MARSCHER
PRIMARY EXAMINER